IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, Plaintiff, v. FOOD & DRUG ADMINISTRATION; DR. STEPHEN M. HAHN, *Commissioner of Food & Drugs, in his official capacity*; BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUTHORITY; GARY L. DISBROW, *Ph.D., Acting Director, Biomedical Advanced Research & Development Authority, in his official capacity*; DEPARTMENT OF HEALTH & HUMAN SERVICES; and ALEX AZAR, *Secretary of Health & Human Services, in his official capacity*, Defendants.	)	No. 1:20-cv-0493

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

The Association of American Physicians & Surgeons ("AAPS" or "Plaintiff") seeks declaratory and injunctive relief against the federal Department of Health & Human Services ("HHS"), two of its constituent agencies – the Food and Drug Administration ("FDA") and the Biomedical Advanced Research & Development Authority ("BARDA") – and their respective lead officers (collectively, "Defendants"), based on the following allegations.

NATURE OF THE ACTION

1. AAPS brings this action on behalf of its members and their patients to end the irrational interference by the FDA with timely access to hydroxychloroquine ("HCQ"), which has been donated in large quantities to the federal government for prompt distribution. Specifically, AAPS seeks an injunction against the FDA's Emergency Use Authorization dated March 28, 2020 ("EUA"), which prohibits use of the donated HCQ except for already-hospitalized patients for

whom clinical trials are unavailable.

2. Through a biased, unlawful process described in greater detail below, FDA officials from prior administrations acted contrary to the wishes of President Donald Trump, by arbitrarily limiting use of HCQ from the Strategic National Stockpile (SNS) "to prescribe to adolescent and adult patients hospitalized with COVID-19, as appropriate, when a clinical trial is not available or feasible."[1]

3. Specifically, a Barack Obama-appointed official who is outspokenly critical of President Trump, Rick Bright, personally opposed making HCQ widely available to the public from the federal SNS,[2] and distorted the agency process to arbitrarily and unjustifiably limit access by patients to HCQ received as donations by the federal government for the purpose of making it available promptly to the public.

4. HCQ has been approved as safe by the FDA for sixty-five (65) years,[3] and is safer than numerous medications that are widely available over the counter ("OTC") without requiring a prescription, including anti-depressants (St John's Wort), sleeping pills (diphenhydramine), bronchodilators (ephedrine), many pain medications including ibuprofen, acetaminophen (Tylenol®), and even aspirin. HCQ is not addictive in any way.

5. President Donald Trump himself has repeatedly praised HCQ, and he announced on May 18, 2020 that on his own initiative and with his physician's advice and prescription, Trump

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1 https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidtherapeutics (viewed 5/31/20).

2 https://www.statnews.com/2020/04/24/why-rick-bright-involved-hydroxychloroquine/ (viewed 5/31/20).

3 https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=reportsSearch.process&rptName=1&reportSelectMonth=4&reportSelectYear=1955&nav (viewed 5/31/20).

took a full regimen of HCQ himself as a prophylaxis against COVID-19, as other world leaders have reportedly been doing.

6. The arbitrary, irrational, and unjustifiable interference by Defendants with the use of HCQ as a prophylaxis interferes with the political process by which the United States selects its president: national political conventions. For nearly two centuries, thousands of delegates attend a national political convention together to nominate their candidate for president and to present their slate to the American public. Continued, irrational interference by Defendants with a safe prophylaxis for COVID-19 has the effect of infringing on the right of the people to hold national political conventions, which have been an essential part of our presidential elections since at least 1832.

7. Efforts to persuade the FDA to remove its irrational limitations of hospitalization and non-availability of a clinical trial have been unsuccessful and petitioning the FDA amid the conflicts of interests among its officials would be futile on this issue.

8. These arbitrary, irrational, and unjustifiable limitations by the FDA in its EUA prevents the use of HCQ as a prophylaxis in nursing homes and when in the best interests of non-hospitalized patients.

9. HCQ, like most medications, loses its efficacy over time, particularly at warmer temperatures which are occurring now as summer approaches. Most of the HCQ doses in the SNS will be discarded for their loss in efficacy if the FDA restrictions on its use are not promptly lifted.

10. There will be irreparable, immediate harm to AAPS members and their patients if the arbitrary, irrational, and unjustifiable restrictions by FDA on use of HCQ from the SNS are not enjoined and declared invalid immediately.

PARTIES

11. Plaintiff AAPS was founded in 1943 and is a nonprofit membership organization

of physicians in virtually all specialties. AAPS is incorporated under the laws of Indiana and headquartered at 1601 N. Tucson Blvd., Suite 9, in Tucson, Arizona. AAPS membership includes physicians practicing in this Western District of Michigan. Members of AAPS, including at least one in this district, have been and continue to be harmed irreparably by the FDA's restrictions in its EUA.

12. Defendant HHS is a federal executive agency, and defendants FDA and BARDA are constituent agencies within HHS.

13. Defendant Stephen M. Hahn is the Commissioner of Food & Drugs, who is the lead officer within the FDA.

14. Defendant Gary L. Disbrow is BARDA's Acting Director, who is the lead officer within BARDA.

15. Defendant Alex Azar is the Secretary of Health & Human Services, who is the lead officer within HHS.

JURISDICTION AND VENUE

16. This action arises out of Defendants' ongoing violations of the equal protection component of the Due Process Clause, U.S. CONST. amend. V, cl. 4, Section 564 of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 360bbb-3, and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706, and thus raises federal questions over which this Court has jurisdiction pursuant to 28 U.S.C. § 1331.

17. Venue is proper in this United States District Court for the Western District of Michigan, under 28 U.S.C. § 1391(e)(1), because Defendant FDA resides in this district by virtue of having an office at 410 W. Michigan Ave, Kalamazoo, Michigan 49007, and Plaintiff has at least one member here who has been injured by virtue of Defendants' actions at issue. If necessary for venue, Plaintiff's members could become named plaintiffs.

18. An actual and justiciable controversy exists between Plaintiffs and Defendants.

19. As set forth in more detail below, members of Plaintiff AAPS have suffered injury in the form of the denial by the FDA of access to HCQ for AAPS members to prescribe to patients. This causes economic injury to AAPS members by interfering with their ability to care for patients who have COVID-19 or who are at risk for it.

20. Because this Court has jurisdiction as a threshold matter, the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, provides this Court the power to "declare the rights and other legal relations of any interested party …, whether or not further relief is or could be sought." 28 U.S.C. § 2201; *accord* FED. R. CIV. P. 57 advisory committee note ("the fact that another remedy would be equally effective affords no ground for declining declaratory relief").

CONSTITUTIONAL AND STATUTORY BACKGROUND

21. The Due Process Clause of the Fifth Amendment includes an equal-protection component that is coextensive with the equal-protection guarantees of the Equal Protection Clause of the Fourteenth Amendment.

22. At a minimum, under those equal protection guarantees, the government cannot treat similarly situated groups or persons differently without a rational basis for doing so.

23. Upon finding an equal-protection violation, a reviewing court's remedy can "level up" the disparate treatment of the disfavored class (*e.g.*, provide greater access to HCQ).

24. Congress enacted the Pure Food and Drugs Act, ch. 3915, 34 Stat. 768 (1906), under its Commerce Power. In 1938, Congress amended and replaced that Act with the FFDCA. PUB. L. NO. 75 -717, 52 Stat. 1040 (1938) (codified, as amended, at 21 U.S.C. §§ 301-399i).

25. In enacting the FFDCA, Congress was clear that the FFDCA *does not* define the practice of medicine. *See* S. REP. NO. 74-361, at 3 (1935) (FFDCA is "not intended as a medical practices act and [would] not interfere with the practice of the healing art[s]").

26. FDA has expressly recognized the freedom that health care professionals possess to use and prescribe approved drugs off-label: "[O]nce a [drug] product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling." 59 Fed. Reg. 59, 820, 59, 821-22 (Nov. 18, 1994) (internal quotation marks omitted, alterations in original).

27. Health care professionals may lawfully prescribe or use an FDA-approved drug both for any uses suggested on the labeling itself (*i.e.*, "on-label uses") and in ways that are not prescribed, recommended, or suggested on the FDA-approved labeling (*i.e.*, "off-label uses").

28. Off-label use of prescription drugs accounts for roughly 20% of all prescriptions, and in some medical specialties it accounts for a majority of prescriptions. Many off-label uses have become the standard of medical care.[4] For generic medication such as HCQ, on which any patent rights have long since expired, there is no financial incentive for any entity to fund expensive studies to seek approval by the FDA for off-label uses, and such approval is not customarily sought or granted.

29. Section 4(a) of the Project Bioshield Act of 2004, PUB. L. NO. 108-276, §4(a), 118 Stat. 835, 853-859, added Section 564 to the FFDCA, codified as 21 U.S.C. § 360bbb-3. Under that section, the Secretary of HHS can authorize the emergency use of either or both unapproved medical products and/or unapproved uses of approved medical products, 21 U.S.C. § 360bbb-3(a)(1)-(4), upon recognizing or declaring an emergency under the criteria outlined in 21 U.S.C. § 360bbb-3(b)(1)(A)-(D).

30. In such an emergency, the statutory criteria for granting an emergency use

[4] David C. Radley; Stan N. Finkelstein; Randall S. Stafford (2006). "Off-label Prescribing Among Office-Based Physicians". *Archives of Internal Medicine*. 166 (9): 1021–1026.

application are that the Secretary of HHS concludes the following:

> (1) that an agent referred to in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;
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> (2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—
>
> > (A) the product may be effective in diagnosing, treating, or preventing—
> >
> > > (i) such disease or condition; or
> >
> > > (ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this chapter, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and
> >
> > (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;
>
> (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition;
>
> (4) in the case of a determination described in subsection (b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and
>
> (5) that such other criteria as the Secretary may by regulation prescribe are satisfied.

21 U.S.C. § 360bbb-3(c)(1)-(5).

31. Neither FDA nor HHS nor any other federal agency has promulgated a regulation pursuant to 21 U.S.C. § 360bbb-3(c)(5) to establish criteria that Defendants may consider in granting an EUA under 21 U.S.C. § 360bbb-3(c).

32. Section 1557 of the Affordable Care Act prohibits discrimination in health programs and activities by not only recipients of federal funds but also federal agencies:

> [A]n individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 …, the Age Discrimination Act of 1975 …, or section 504 of the Rehabilitation Act of 1973 …, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title[.]

42 U.S.C. § 18116(a).

33. The entity Defendants – HHS, FDA, and BARDA – are "Executive Agencies" within the meaning of Section 1557 of the Affordable Care Act, and the SNS is a "health program or activity" within the meaning of that section.

34. As relevant here, the judicial-review provisions of the APA proscribe agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The APA further bars agency action that is "in excess of statutory jurisdiction, authority, or limitations," *Id.* at § 706(2)(C), and directs courts to "hold unlawful and set aside agency action, findings, and conclusions found to be … contrary to constitutional right, power, privilege or immunity." 5 U.S.C. § 706(2)(B).

ALLEGATIONS RELEVANT TO ALL COUNTS

35. COVID-19 has reportedly caused the death of more than 100,000 Americans in merely a few months this year, roughly half of whom have contracted and died from this disease while residing in nursing homes.

36. By denying elderly nursing-home patients access to HCQ when COVID-19 affects those patients more severely than younger patients, the EUA disparately impacts the elderly and thus discriminates on the basis of age within the meaning of Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116, and the Age Discrimination Act of 1975.

37. By the end of May 2020, pharmaceutical companies donated more than 150 million

doses of hydroxychloroquine (HCQ) – enough to fully treat more than 15 million people – to the federal government for immediate use in treating COVID-19, and as part of their efforts for the "prevention and treatment of the coronavirus outbreak."[5]

38. Yet the vast majority of these 150 million doses of HCQ have not been distributed to the public and are in imminent danger of spoilage due to the passage of time amid the increasing temperatures as summer approaches.

39. Multiple foreign governments, including China, India,[6] South Korea, Costa Rica, United Arab Emirates, and Turkey, successfully recommend use of HCQ for effective early treatment of COVID-19, and for use as a prophylaxis for the disease. Multiple studies confirm the effectiveness of HCQ as an early treatment of COVID-19.

40. For example, a recent study in India, where HCQ is being widely used as a prophylaxis, concluded that:

> The pivotal finding of our study was the noteworthy benefits of HCQ prophylaxis. … [T]he National Task Force for COVID-19 in India recommended once a week maintenance dose for seven weeks (400 mg once weekly), following the loading dose (400 mg bd).[7]

41. There are no peer-reviewed or meritorious studies showing a lack of HCQ safety for COVID-19 patients. The retrospective studies cited in the media to the contrary are too flawed to inform rational decisionmaking because they compare outcomes without involving like patient populations (e.g., the HCQ patients may have been more sick than the non-HCQ patients or may have come from geographic areas with more acute exposures, which would explain higher rates of negative outcomes without showing in any way that HCQ caused or contributed to those

[5] https://phrma.org/en/Coronavirus/PhRMA-Member-Efforts (viewed 5/31/20).

[6] https://theprint.in/health/hcq-breakthro...se/427583/ (viewed 5/31/20).

[7] http://www.ijmr.org.in/temp/IndianJMedRes000-5386406_145744.pdf (p. 6, viewed 6/2/20).

outcomes).

42. There is dramatic difference in saving lives in countries allowing early and prophylactic use of hydroxychloroquine compared with the United States, as of the third week in May 2020:

Country	# of cases	# of deaths	Deaths/million	Use of HCQ
India	101,261	3,164	2.0	Early and prophylactic
Costa Rica	866	10	2.0	Early and prophylactic
Australia	7,068	99	4.0	Early and prophylactic
South Korea	11,078	263	5.0	Early and prophylactic
Argentina	8,371	382	8.0	Early and prophylactic
Turkey	150,593	4171	50.0	Early and prophylactic
Israel	16,643	276	32.0	Early and prophylactic use
Brazil	255,368	16,853	79.0	Early, some prophylactic use
U.S.	1,550,294	91,981	278.0	Late, in hospitalized patients

43. As explained by experts in a recent article published by the *New York Times*:

> Acting before or very soon after an infection is the best way to handle most acute viral diseases. Why aren't we focusing on that with Covid-19? … [W]e believe that trials of prophylactic and therapeutic drugs for asymptomatic and mild cases of Covid-19 have a greater chance of success than does administering drugs to critically ill patients — as well as greater long-term potential to benefit more people overall.

Richard Malley and Marc Lipsitch, "Acting before or very soon after an infection is the best way to handle most acute viral diseases. Why aren't we focusing on that with Covid-19?" *New York Times* (May 23, 2020).

44. An eminent Professor of Epidemiology in the Department of Epidemiology and Public Health at the Yale School of Public Health and Yale School of Medicine, Harvey A. Risch, stated likewise in a peer-reviewed medical journal:

> An outpatient treatment that prevents hospitalization is desperately needed

> [for COVID-19]. … Hydroxychloroquine+azithromycin has been widely misrepresented in both clinical reports and public media …. Evidence about use of hydroxychloroquine alone, or of hydroxychloroquine+azithromycin in inpatients, is irrelevant concerning efficacy of the pair in early high-risk outpatient disease. Five studies, including two controlled clinical trials, ***have demonstrated significant major outpatient treatment efficacy***. Hydroxychloroquine+azithromycin has been used as standard-of-care in more than 300,000 older adults with multicomorbidities, with estimated proportion diagnosed with cardiac arrhythmias attributable to the medications 47/100,000 users, of which estimated mortality is <20%, 9/100,000 users, compared to the 10,000 Americans now dying each week. ***These medications need to be widely available*** and promoted immediately for physicians.

Harvey A Risch, *Early Outpatient Treatment of Symptomatic, High-Risk Covid-19 Patients That Should Be Ramped-Up Immediately as Key to the Pandemic Crisis*, __ AM. J. EPIDEMIOLOGY ___ (May 27, 2020) (forthcoming 2020) (emphasis added).[8]

45. The BBC reported on the success of Turkey in keeping its mortality low from COVID-19:

> Chief doctor Nurettin Yiyit … says it's key to use hydroxychloroquine early. "Other countries are using this drug too late," he says, "especially the United States. We only use it at the beginning. We have no hesitation about this drug. We believe it's effective because we get the results."

Orla Guerin, *Coronavirus: How Turkey took control of Covid-19 emergency*, BBC News (May 29, 2020).[9]

46. National Public Radio recently quoted the expert Dr. Jon Giles, an epidemiologist and rheumatologist at Columbia University Department of Medicine, about the safety of HCQ:

> "It's a very, very safe drug; it's been used for over 75 years. When I give someone hydroxychloroquine, I don't get an ECG or do blood

[8] https://academic.oup.com/aje/advance-article/doi/10.1093/aje/kwaa093/5847586 (viewed 6/1/20).

[9] https://www.bbc.com/news/world-europe-52831017# (viewed 5/31/20).

monitoring."[10]

47. More than 25 articles since 1982 published in peer-reviewed medical journals have reported on the safety of HCQ, and these articles are included in the PubMed database as maintained by the United States National Library of Medicine at the National Institutes of Health.

48. The Centers for Disease Control and Prevention ("CDC"), which is a division within Defendant HHS, declares the safety of HCQ in one of its publications posted on its website:

> How long is it safe to use hydroxychloroquine?
>
> CDC has no limits on the use of hydroxychloroquine for the prevention of malaria. When hydroxychloroquine is used at higher doses for many years, a rare eye condition called retinopathy has occurred. People who take hydroxychloroquine for more than five years should get regular eye exams.[11]

49. The President of El Salvador, Nayib Bukele, announced that he is taking hydroxychloroquine as a prophylaxis against COVID-19, and that most world leaders were doing likewise: "I use it as a prophylaxis. President Trump uses it as a prophylaxis. Most of the world's leaders use it as a prophylaxis," said President Bukele.[12]

50. On May 31, 2020, the United States and Brazil issued a joint statement regarding health cooperation, which is posted on the White House's website and provides in part the following:

> The American and Brazilian people stand in solidarity in the fight against the coronavirus. Today, as a demonstration of that solidarity, we are announcing the United States Government has delivered two million doses

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[10] https://www.npr.org/sections/health-shots/2020/05/21/859851682/politics-around-hydroxychloroquine-hamper-science (viewed 5/31/20).

[11] https://www.cdc.gov/malaria/resources/pdf/fsp/drugs/Hydroxychloroquine.pdf (p. 2, viewed 6/1/20).

[12] https://www.cnn.com/2020/05/27/americas/salvador-president-coronavirus-hydroxychloroquine-intl/index.html (viewed 5/31/20).

> of hydroxychloroquine (HCQ) to the people of Brazil. ...
>
> HCQ will be used as a prophylactic to help defend Brazil's nurses, doctors, and healthcare professionals against the virus. It will also be used as a therapeutic to treat Brazilians who become infected.[13]

Disregard of President Trump's Policy by Agency Officials

51. Rick Bright, Ph.D., an outspoken critic of President Trump, was the Director at BARDA as appointed by prior President Barack Obama.

52. Bright strongly favors vaccination for COVID-19, even though no such vaccine is available, and some experts doubt the feasibility of developing a timely vaccine for this novel virus.[14]

53. At all relevant times Bright has opposed making HCQ widely available for physicians to prescribe to patients in connection with COVID-19.[15]

54. According to a whistleblower complaint against the Trump Administration submitted by Bright, FDA Director of the Center for Drug Evaluation and Research Janet Woodcock also played a pivotal role in pushing for the EUA.

55. Woodcock also occupied a top position in a public-private operation designed to approve new vaccines for COVID-19, and she reportedly communicated with a Wall Street analyst concerning such development.

56. Prophylactic use of HCQ is a rival approach to vaccination, but Woodcock did not recuse herself from the decision-making at the FDA concerning the EUA restrictions on access to

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[13] https://www.whitehouse.gov/briefings-statements/joint-statement-united-states-america-federative-republic-brazil-regarding-health-cooperation/ (viewed 6/1/2020).

[14] https://www.techtimes.com/articles/249779/20200520/hiv-scientist-doubts-coronavirus-vaccine-claims-social-distancing-is-better-to-fight-covid-19.htm (viewed 5/31/20).

[15] *See* footnote 2, *supra*.

HCQ.

57. After an advocacy group objected to a conflict of interest by Woodcock in her various roles, she recused herself from the review process for vaccination[16] but remains non-recused from decision-making that sharply and unjustifiably limits access to HCQ.

58. Bright and agency officials working with him have been biased by their opposition to President Trump and/or their support of rival treatments other than HCQ, such as remdesivir as advocated by Bright and vaccination as sought by Woodcock.

59. Specifically, Bright favors an expensive, proprietary antiviral medication developed by Gilead Sciences ("Gilead"). Bright formed the following pre-conceived opinion in favor of Gilead which should have caused his recusal from the decision-making process about HCQ:

> Gilead's supply of the drug [*i.e.*, remdesivir] was low – it had only a few thousand doses of the drug on hand and the timeline to manufacture more was lengthy. ***[Bright] repeatedly advised Dr. Kadlec and other HHS officials of the urgent need to acquire the existing doses and to secure future doses as they were produced***. He also strongly recommended that HHS work with Gilead to "on-shore" all steps of the Remdesivir supply chain to ensure an uninterrupted supply in the United States.[17]

60. At the improper insistence of Bright, before he was relieved of his HCQ-related duties by the Trump Administration, on March 28, 2020 the FDA arbitrarily limited use of HCQ from the SNS as follows.

The EUA

61. The FDA issued its EUA as a Letter from Denise M. Hinton, Chief Scientist, Food

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16 https://endpts.com/covid-19-roundup-hit-with-new-conflict-accusations-janet-woodcock-steps-out-of-the-agencys-covid-19-chain-of-command/ (viewed 5/31/20).

17 https://www.kmblegal.com/sites/default/files/NEW R. Bright OSC Complaint_Redacted.pdf (emphasis added, viewed 5/31/20).

& Drug Admin., to Rick Bright, Ph.D., Director, Biomedical Advanced Research & Development Authority, Request for Emergency Use Authorization For Use of Chloroquine Phosphate or Hydroxychloroquine Sulfate Supplied From the Strategic National Stockpile for Treatment of 2019 Coronavirus Disease (Mar. 28, 2020). The disputed portion of the EUA are the hospitalization and clinical-trial restrictions in its "Scope of Authorization" as follows:

> The hydroxychloroquine sulfate may only be used to treat adult and adolescent patients who weigh 50 kg or more ***hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible***.

EUA, at 4 (emphasis added).[18]

62. These restrictions deny patients the use of HCQ for its prophylactic effect (*i.e.*, the "with COVID-19" limit requires that the patient *have* COVID-19), deny non-hospitalized patients (such as nursing home residents and patients who visit physicians' offices) access to HCQ, and even deny or restrict access to hospitalized patients for whom clinical trials are available.

63. In the EUA, Defendants state that the criteria for an EUA are met with respect to the existence of an emergency for the COVID-19 pandemic under 21 U.S.C. § 360bbb-3(b), that the COVID-19 virus can cause serious or life-threatening diseases or conditions under § 360bbb-3(c)(1), that HCQ is or may be effective in treating or preventing the COVID-19 virus under § 360bbb-3(c)(2)(A)(i), and that there is no adequate, approved, and available alternative to HCQ under § 360bbb-3(c)(3).[19]

64. Neither the EUA itself nor Defendants invoked the scarcity of HCQ as a basis for rationing access to HCQ. Nor could they, given the plentiful supply of the easy-to-manufacture

[18] *See* footnote 1, *supra*.

[19] The Secretary of Defense did not request the EUA; as such, the criteria of 21 U.S.C. § 360bbb-3(c)(4) are not germane to the challenged EUA. Defendants have not promulgated additional regulatory criteria pursuant to 21 U.S.C. § 360bbb-3(c)(5), and thus it adds no additional criteria for the issuance of an EUA.

HCQ which has limited shelf life in the SNS amid warming temperatures.

65. The EUA-related criterion in dispute is whether the limitations in the EUA's "Scope of Authorization" is necessary under § 360bbb-3(c)(2)(A) with respect to patients who are not "hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible." Defendants give two rationales for these restrictions in the EUA: (1) "The safety profile of these drugs has only been studied for FDA approved indications, not COVID-19;" and (2) "FDA encourages the conduct and participation in randomized controlled clinical trials that may produce evidence concerning the effectiveness of these products in treating COVID-19." EUA, at 2.

66. Defendants' first rationale is a strawman, because safety is determined with respect to patients, not diseases. HCQ has been proven to be safe for 65 years and has been fully approved by the FDA as safe throughout this entire period.

67. The EUA misleads the public with its first rationale by falsely pretending that a medication approved as safe for treating one disease can somehow not be safe for treating another disease.

68. The EUA further misleads the public with its first rationale by falsely implying that medication approved as safe for one use requires time-consuming additional studies of safety before it may properly be used to treat a new disease.

69. In fact, the "safety profile" with respect to new uses of a medication previously approved by the FDA is virtually never studied, and there is no rational basis for delaying new uses of previously approved medication by requiring such studies.

70. With respect to patients with COVID-19 who are not hospitalized, the FFDCA, the Constitution's federalist structure, and the presumption against preemption all suggest that Congress did not intend Defendants to supersede a prescribing medical professional's judgment

for off-label uses of FDA-approved drugs for patients.

71. With respect to patients not infected with COVID-19 for whom HCQ is prescribed or sought for HCQ's prophylactic effect, EUA's stated safety concern about HCQ's effect on patients ***infected with*** COVID-19 does not apply to patients ***not infected with*** COVID-19.

72. With respect to the EUA's seeking to push patients into clinical trials in lieu of having their medical professional prescribe the drug, Defendants lack the authority to limit access that way. Significantly, not everyone who participates in a "randomized controlled clinical trial" even receives the drug in question, as usually half of participants in a clinical trial receive a placebo and thus would not receive any HCQ.

73. The EUA discriminates against everyone who is outside of a hospital: residents of nursing homes, physicians who care for nursing home patients, physicians having office practices, and patients who are treated in connection with office visits.

74. The EUA also discriminates against those who would receive only a placebo, and not HCQ, in a clinical study arbitrarily required by the EUA.

75. The discrimination against these millions of people threatens to cause the unnecessary loss of life and unnecessary illness and thereby injures AAPS members and their patients.

76. Multiple studies suggest that HCQ is more effective if used early in the progression of COVID-19, as other antiviral medication like oseltamivir (Tamiflu®) is, and the blanket federal limitations in the EUA are arbitrary, irrational, and unjustified in interfering with early treatment by HCQ.

77. There is no need to ration or restrict access to HCQ, as the stockpile contains enough to serve 15 million Americans and it is feasible for manufacturers to produce a million

new doses of HCQ daily.

78. These arbitrary, irrational, and unjustifiable limitations by the FDA prevent the use of HCQ as a prophylaxis, as President Trump and other world leaders are using it, and prevent nursing home residents from receiving it, where more than half of the COVID-19 mortalities have reportedly occurred.[20]

79. Never before in the history of the United States has an "emergency ***use*** authorization" been issued to ***restrict the use*** of an old and safe medication, as Defendants have improperly done with respect to HCQ. The EUA restrictions on the use of the long-approved medications is outside the scope of any statutory authorization.

80. As is customary, state regulatory officials have imitated or relied upon the unjustified FDA policy,[21] as commanded by the Federation of State Medical Boards ("FSMB").

81. The FSMB – which directs state medical boards that wield complete authority over licenses to practice medicine – relied on the EUA to order that:

> Physicians, nurses, pharmacists, pharmacies and hospitals have an ethical duty to put the needs of patients first, and this includes observing strict prescribing guidelines. On March 28, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for use of oral formulations of chloroquine phosphate and hydroxychloroquine sulfate. The authorization allows these medications to be prescribed by clinicians for hospitalized adult and adolescent patients "for whom a clinical trial is not available, or participation is not feasible." Clinicians should avoid prescribing for themselves or their family members and should be aware that ***deviating from the standard of care could put their license at risk***.[22]

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[20] https://www.theguardian.com/us-news/2020/may/11/nursing-homes-us-data-coronavirus (viewed 5/31/20).

[21] https://www.lawyersinlafayette.com/2020/04/covid-19-warning-from-medical-board-re-prescriptions/ (viewed 5/31/20).

[22] http://www.fsmb.org/siteassets/advocacy/pdf/fsmb-nabp-joint-statement-covid-19-prescribing-fsmb-edits.pdf (emphasis added, viewed 5/31/20).

Ripeness

82. The EUA is "final agency action for which there is no other adequate remedy." 5 U.S.C. § 704. The EUA represents FDA's consummated decision-making process to grant Bright's request with his limitations. Further, the EUA was a decision from which rights or obligations were determined and from which legal consequences (*e.g.*, access to HCQ from the SNS) flowed.

83. Plaintiff has no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

84. Plaintiff has no adequate remedy at law.

Injury to AAPS Members

85. Defendant FDA's unlawful action has caused injury to a physician member of Plaintiff AAPS ("Dr. John Doe").

86. Physician Dr. John Doe has been unable to successfully prescribe a full regimen of HCQ for patients in need of it, due to the FDA's unlawful and irrational EUA.

87. Patients of Dr. John Doe have been additionally harmed by the FDA's EUA by being denied access to a full regimen of the potentially lifesaving HCQ.

88. Dr. John Doe practices within the Western District of Michigan and has patients who reside in Kalamazoo, Michigan.

89. Another physician member of AAPS was prevented from successfully prophylactically treating his nursing home patients with HCQ by virtue of the FDA's EUA.

90. Numerous physician members of AAPS, including Dr. John Doe, reasonably fear retaliation against them by state medical boards based on the irrational restrictions in the EUA along with their incorporation into the directive made to state medical boards by the FSMB.

Disparate Impact of FDA Policy on Religious Services

91. Access to a prophylaxis and early treatment of COVID-19 is particularly important to reopening religious services without a chilling effect which denial of timely access to treatment causes.

92. About a quarter (25%) of weekly attendees of all kinds of religious services are over 65 years old,[23] who are thereby at higher risk from COVID-19 than other demographic groups, such as young and healthy adults.

93. Clergy are often in contact with people who particularly vulnerable to contagion, such as those suffering from other medical conditions.

94. The withholding and denial of access to prophylactic and early treatment by HCQ has a disparate impact on attendance at religious services, which AAPS members and their patients have a constitutional right to attend.

95. A lawsuit is pending in *Beemer v. Whitmer*, 1:20-cv-00323-PLM-PJG (W.D. Mich.), which challenges on constitutional grounds the closure of churches in Michigan.

96. Like arguments made in that lawsuit, those at high risk for COVID-19 (including AAPS members) who attend church services should not be arbitrarily denied access by Defendants to prophylactic and early treatment by HCQ.

CAUSES OF ACTION

COUNT I
(EQUAL PROTECTION)

97. Plaintiff AAPS incorporates herein all statements and allegations contained in this Complaint.

[23] https://www.pewforum.org/religious-landscape-study/attendance-at-religious-services/ (viewed 5/31/20).

98. In issuing the EUA's restrictions to limit access to HCQ to patients who are hospitalized without feasible access to a clinical trial, Defendants violated the equal protection guarantee implicit in the Due Process Clause of the Fifth Amendment to the U.S. Constitution. The EUA impermissibly discriminates based on a patient's hospitalization status, illness status, and access to clinicals trial, without a rational basis for this discrimination.

99. The doctrine of administrative exhaustion does not apply to constitutional violations.

100. With respect to patients who wish to use HCQ, and medical professionals who wish to prescribe HCQ for its prophylactic effect to prevent becoming infected with the COVID-19 virus, the EUA's limitation to hospitalized patients with COVID-19 lacks a rational basis for a drug that FDA already has found to be safe.

101. With respect to hospitalized patients with COVID-19 who have feasible access to clinical trials, Defendants lack the authority to compel participation in randomized controlled clinical trials that might not provide particular patients any access to HCQ at all.

102. With respect to non-hospitalized patients with COVID-19, Defendants lack the authority to override the discretion of a duly licensed medical professional to prescribe off-label uses of FDA-approved drugs.

103. The EUA's unlawful discrimination against the elderly under Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116, *per se* lacks a rational basis.

104. Inherent in the constitutional right to attend religious services is a right to equal access to prophylactic and early treatment for a disease which may be transmitted during such services.

105. For the foregoing reasons, the challenged EUA violates the equal-protection

component of the Fifth Amendment's Due Process Clause and is contrary to the constitutional authority of Defendants.

COUNT II
(ADMINISTRATIVE PROCEDURE ACT)

106. Plaintiff AAPS incorporates herein all statements and allegations contained in this Complaint.

107. In addition to violating constitutional equal protection guarantees as alleged above and incorporated herein, the EUA is also arbitrary and capricious and exceeds Defendants' lawful authority under the APA.

108. Defendants lack authority under FFDCA Section 564 or any other provision to limit access to a drug based on the patient's ability to participate in a clinical trial.

109. The decision-making underlying the EUA was tainted by bias, and thus it is arbitrary and capricious.

110. The EUA's unlawful discrimination against the elderly under Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116, *per se* constitutes arbitrary and capricious action and action not otherwise in accordance with the law.

111. For the foregoing reasons, the challenged EUA is arbitrary, capricious, not otherwise in accordance with the law, and in excess of authority granted by law.

COUNT III
(FIRST AMENDMENT ASSOCIATIVE RIGHTS)

112. Plaintiff AAPS incorporates herein all statements and allegations contained in this Complaint.

113. Plaintiff AAPS's members have First Amendment rights of association that depend on access to safe prophylaxis medication during a pandemic, because otherwise they are prohibited from or instructed not to gather in large groups.

114. Defendants have infringed on these associative rights of Plaintiff AAPS's members by denying them access to HCQ, which has been proven to be safe for more than 65 years.

115. Defendants do not have a compelling or even a rational basis for impeding access to HCQ as a potential prophylaxis for COVID-19.

116. As a result of Defendants' actions, AAPS has already had to cancel one of its scheduled conferences and its annual conference is in jeopardy; the Republican National Convention is also unnecessarily jeopardized to the detriment of members of AAPS and the entire Nation.

117. Defendants' foregoing infringement on associative rights has caused, and continues to cause, irreparable harm to Plaintiff AAPS.

PRAYER FOR RELIEF

118. WHEREFORE, Plaintiff AAPS respectfully asks this Court to grant the following relief:

A. Enter judgment in favor of Plaintiff AAPS and against Defendants on all counts.

B. Pursuant to 28 U.S.C. §§ 1331, 2201-2202, and FED. R. CIV. P. 57, issue a Declaratory Judgment that the restrictions in the EUA that currently require being hospitalized, having COVID-19, and facing the non-availability of a clinical trial prior to obtaining HCQ from the SNS are invalid.

C. Pursuant to 28 U.S.C. §§ 1331, 2201-2202, and FED. R. CIV. P. 57, issue an Injunction providing that:

(i) All Defendants are enjoined from enforcing the restrictions in the EUA that currently require being hospitalized, having COVID-19, and facing the non-availability of a clinical trial prior to obtaining HCQ from the SNS;

(ii) All Defendants are enjoined to make available and distribute promptly, and for the

benefit of the public holding valid prescriptions, the HCQ being stored in the SNS; and

(iii) All Defendants are enjoined from impeding the distribution, sale or purchase of HCQ by adult members of the public during the COVID-19 pandemic.

D. Pursuant to 28 U.S.C. § 2412 and any other applicable provisions of law or equity, award Plaintiffs' costs and reasonable attorneys' fees.

E. Such other relief as may be just and proper.

Dated: June 2, 2020

Respectfully submitted,

/s/ Lawrence J. Joseph

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